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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/052,092	
	Filing Date	January 18, 2002	
	First Named Inventor	Suzanne Fuqua	
	Group Art Unit	N/A	
	Examiner Name	Not Yet Assigned	
Total Number of Pages in This Submission	8	Attorney Docket Number	HO-P02102US2

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Date	October 29, 2002

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Ronnie Webb
(Ronnie Webb)

Docket No.: HO-P02102US2
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Suzanne Fuqua, et al.

Application No.: 10/052,092

Group Art Unit: N/A

Filed: January 18, 2002

Examiner: Not Yet Assigned

For: METHODS AND COMPOSITIONS IN
BREAST CANCER DIAGNOSIS AND
THERAPEUTICS

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned.

A copy of each reference on PTO/SB/08 is attached.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other

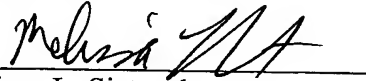
Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 06-2375, under Order No. HO-P02102US2.

Dated: October 29, 2002

Respectfully submitted,

By



Melissa L. Sistrunk

Registration No.: 45,579

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				Application Number	10/052,092
				Filing Date	January 18, 2002
				First Named Inventor	Suzanne Fuqua
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	4	Attorney Docket Number	HO-P02102US2

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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	5563035-	10-08-1996	Weigel	
	AB	6162606-	12-19-2000	Raam	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 4

Complete if Known

Application Number 10/052,092
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First Named Inventor Suzanne Fuqua
Art Unit N/A
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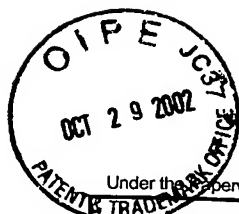
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Burstein, Nelson A.; Overall Principles of Cancer Management - Hormone Therapy; published in Cancer, A Manual for Practitioners (American Cancer Society Massachusetts Division); 6th Edition, 1982, pages 67 - 71	
	CB	Donegan, William L.; Prognostic Factors; Cancer 1992; 70:1755 - 1764	
	CC	Brooks, S. C., et al.; Relation of Tumor Content of Estrogen and Progesterone Receptors with Response of Patient to Endocrine Therapy; Cancer 46:2775 - 2778, 1980	
	CD	Degenshein, George A., et al.; The Value of Progesterone Receptor Assays in the Management of Advanced Breast Cancer; Cancer 46:2789 - 2793, 1980	
	CE	Fugua, Suzanne A. W., et al.; Variant Human Breast Tumor Estrogen Receptor with Constitutive Transcriptional Activity; Cancer Research 51:105 - 109, January 1, 1991	
	CF	Gelbfish, Gary A., et al.; Relationship of Estrogen and Progesterone Receptors to Prognosis in Breast Cancer; Ann Surg. 207(1):75 - 79, January 1998	
	CG	Greene, Geoffrey, et al.; Sequence and Expression of Human Estrogen Receptor Complementary DNA; Science Vol. 231, pages 1150 - 1154; March 7, 1986	
	CH	Kohail, Hanaa M., et al.; A Multifactorial Analysis of Steroid Hormone Receptors in Stages I and II Breast Cancer; Ann. Surg 201(5):611 - 617, May, 1985	
	CI	Elledge, Richard M., et al.; Prognostic Factors and Therapeutic Decisions in Axillary Node-Negative Breast Cancer; Annu. Rev. Med. 1993, 44:201 - 210	
	CJ	McGuire, William L.; Prognostic factors for recurrence and survival in human breast cancer; Breast Cancer Research and Treatment 10:5 - 9, 1987	
	CK	Millis, Rosemary R.; Correlation of Hormone Receptors with Pathological Features in Human Breast Cancer; Cancer 46:2869 - 2871, 1980	
	CL	McCarty, Kenneths, et al.; Correlation of Estrogen and Progesterone Receptors with Histologic Differentiation in Mammary Carcinoma; Cancer 46:2851 - 2858, 1980	
	CM	O'Connell, Peter, et al.; Loss of Heterozygosity at D14S62 and Metastatic Potential of Breast Cancer; REPORTS, Journal of the National Cancer Institute, Vol. 91(16), pages 1391 - 1397; August 18, 1999	
	CN	Shousha, S., et al.; Oestrogen receptors in mucinous carcinoma of the breast: an immunohistological study using paraffin wax sections; J. Clin. Pathol. 1989; 42:902 - 905	
	CO	Shousha, S., et al.; Immunohistological study of oestrogen receptors in breast carcinomas that are biochemically receptor negative; J. Clin. Pathol. 1990; 43:239 - 242	
	CP	Williams, M. R., et al.; Oestrogen receptors in primary and advanced breast cancer: An eight year review of 704 cases; Br. J. Cancer (1987), 55:67 - 73	
	CQ	Vogelstein, Bert, et al.; The multistep nature of cancer; TIG Vol. 9 (4), pages 138 - 141, April 1993	
	CR	Weigel, Ronald J., et al.; Transcriptional Control of Estrogen Receptor in Estrogen Receptor-negative Breast Carcinoma; Cancer Research, Vol. 53 (15):3472 - 3474, August 1, 1993	
	CS	Scott, Gary K., et al.; Truncated Forms of DNA-binding Estrogen Receptors in Human Breast Cancer; J. Clin. Invest. 1991, 88:700 - 706	
	CT	Ince, B. Avery, et al.; Powerful Dominant Negative Mutants of the Human Estrogen Receptor; The Journal of Biological Chemistry, Vol. 268 (19), 14026 - 14032, 1993	
	CU	Fuqua, Suzanne A. W., et al.; Inhibition of Estrogen Receptor Action by a Naturally Occurring Variant in Human Breast Tumors; Cancer Research 52:483 - 486, January 15, 1992	
	CV	Castles, Carl G., et al.; Expression of a Constitutively Active Estrogen Receptor Variant in the Estrogen Receptor-negative BT-20 Human Breast Cancer Cell Line; Cancer Research 53	

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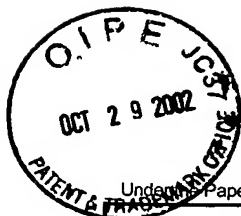
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Sheet 3 of 4

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Application Number	10/052,092
Filing Date	January 18, 2002
First Named Inventor	Suzanne Fuqua
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	HO-P02102US2

		(24):5934 - 5939, December 15, 1993	
•	CW	Keaveney, M., et al.; Evidence for a Previously Unidentified Upstream Exon in the Human Oestrogen Receptor Gene; J. Mol. Endocr., Vol. 6:111 - 115, 1991	
•	CX	Piva, R., et al.; Sequencing of an RNA Transcript of the Human Estrogen Receptor Gene: Evidence for a New Transcriptional Event; J. Steroid Biochem. Molec. Biol., Vol. 46 (5), pages 531 - 538, 1993	
•	CY	McDonnell, Donald P.; The Molecular Pharmacology of SERMs; TEM, Vol. 10 (8):301 - 311, 1999	
•	CZ	Barkhem, Tomas, et al.; Differential Response of Estrogen Receptor a and Estrogen Receptor B to Partial Estrogen Agonists/Antagonists; Molecular Pharmacology, 54:105 - 112, 1998	
•	CA1	Sun, Jun, et al.; Novel Ligands that Function as Selective Estrogens or Antiestrogens for Estrogen Receptor-a or Estrogen Receptor-B; Endocrinology, Vol. 140 (2):800 - 804, 1999	
•	CB1	McDonnell, Donald P., et al.; Cellular Mechanisms Which Distinguish between Hormone- and Antihormone-Activated Estrogen Receptor; Annals New York Academy of Sciences, 761:121 - 137	
•	CC1	Barkhem, Tomas, et al.; Characterization of the "Estrogenicity" of Tamoxifen and Raloxifene in HepG2 Cells: Regulation of Gene Expression from an ERE Controlled Reporter Vector Versus Regulation of the Endogenous SHBG and PS2 Genes; J. Steroid Biochem. Molec. Biol., Vol. 62 (1), pages 53 - 64, 1997	
•	CD1	Cowley, Shaun, M., et al.; Estrogen Receptors a and B Form Heterodimers on DNA; The Journal of Biological Chemistry, Vol. 272 (32), pages 19858 - 19862, August 8, 1997	
✓	CE1	Paige, Lisa A., et al.; Estrogen receptor (ER) modulators each induce distinct conformational changes in ER a and ER B; Proc. Natl. Acad. Sci. USA, Vol. 96, pages 3999 - 4004, March 1999	
	CF1	Shiau, Andrew K., et al.; The Structural Basis of Estrogen Receptor/Coactivator Recognition and the Antagonism of This Interaction by Tamoxifen; Cell, Vol. 95, pages 927 - 937, December 28, 1998	
•	CG1	Cowley, Shaun M., et al.; A comparison of transcriptional activation by ERa and ERB; Journal of Steroid Biochemistry and Molecular Biology, Vol. 69, pages 165 - 175, 1999	
•	CH1	Tremblay, Gilles B., et al.; Cloning, Chromosomal Localization, and Functional Analysis of the Murine Estrogen Receptor B; Molecular Endocrinology 11:353 - 365, 1997	
•	CI1	Witkowska, H. Ewa, et al.; Characterization of bacterially expressed rat estrogen receptor B ligand binding domain by mass spectrometry: Structural comparison with estrogen receptor a; Steroids 62:621 - 631, 1997	
•	CJ1	McGuire, William L., et al.; Estrogen Receptor Variants in Clinical Breast Cancer; Molecular Endocrinology 5:1571 - 1577, 1991	
•	CK1	van Agthoven, Ton, et al.; Differential Expression of Estrogen, Progesterone, and Epidermal Growth Factor Receptors in Normal, Benign, and Malignant Human Breast Tissues using Dual Staining Immunohistochemistry; American Journal of Pathology, Vol. 144 (6), pages 1238 - 1246, June 1994	
•	CL1	Zhang, Ziu-Xia, et al.; An Estrogen Receptor Mutant with Strong Hormone-independent Activity from a Metastatic Breast Cancer; Cancer Research 57:1244 - 1249, April 1, 1997	
•	CM1	Tremblay, Gilles B., et al.; Ligand-independent Activation of the Estrogen Receptors a and B by Mutations of a Conserved Tyrosine Can Be Abolished by Antiestrogens; Cancer Research 58:877 - 881, March 1, 1998	
•	CN1	Anandappa, Shanz Y., et al.; Variant estrogen Receptor a mRNAs In Human Breast Cancer Specimens; Int. J. Cancer: 88, pages 209 - 216, 2000	
•	CO1	Schuur, Eric R., et al.; Monoallelic Amplification of Estrogen Receptor-a Expression in Breast Cancer; Cancer Research 60, pages 2598 - 2601, May 15, 2000	
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				Art Unit	N/A
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				Attorney Docket Number	HO-P02102US2
Sheet	4	of	4		

CP1	Fasco, Michael J., et al.; Expression of an estrogen receptor alpha variant protein in cell lines and tumors; Molecular and Cellular Endocrinology 162, pages 167 - 180, 2000	
CQ1	Rost, Natalia S., et al.; Immunochemical analyses of estrogen receptors in human breast tumors by a novel monoclonal estrogen receptor antibody (EVG F9); Steroids 65, pages 429 - 436, 2000	
CR1	O'Connell, Peter, et al.; Analysis of Loss of Heterozygosity in 399 Premalignant Breast Lesions at 15 Genetic Loci; Journal of the National Cancer Institute, Vol. 90 (9), pages 697 - 703; May 6, 1998	
CS1	Page, David L., et al.; Premalignant and Malignant Disease of the Breast: The Roles of the Pathologist; Mod Pathol 1998; 11(2):120 - 128	
CT1	Page, David L.; The Woman at High Risk for Breast Cancer - Importance of Hyperplasia; Special Problems in Breast Cancer Therapy, Vol. 76 (2), pages 221 - 230, April 1996	
CU1	Roger, Pascal, et al.; Dissociated Overexpression of Cathepsin D and Estrogen Receptor Alpha in Preinvasive Mammary Tumors; Human Pathology, Vol. 31 (5), pages 593 - 600, May 2000	
CV1	Lishman, S. C., et al.; Atypical lobular hyperplasia and lobular carcinoma in situ: surgical and molecular pathology; Histopathology 1999, 35, 195 - 200	
CW1	Page, David L., et al.; Evaluation and Management of High Risk and Premalignant Lesions of the Breast; World J. Surg. 18, 32 - 38, 1994	
CX1	Page, David L., et al.; Anatomic Markers of Human Premalignancy and Risk of Breast Cancer; Cancer 66:1326 - 1335, 1990	
CY1	Cardiff, R. D., et al.; Biology of Breast Preneoplasia; Cancer 39:2734 - 2746, 1977	
CZ1	Stoll, B. A.; Premalignant Breast Lesions: Role for Biological Markers in Predicting Progression to Cancer; European Journal of Cancer, Vol. 35 (5), pages 693 - 697, 1999	
CA2	Slentz-Kesler, Kimberly, et al.; Identification of the Human Mnk2 Gene (MKNK2) through Protein Interaction with Estrogen Receptor B; Genomics 69, 63 - 71, 2000	
CB2	Dupont, William D., et al.; Risk Factors for Breast Cancer in Women with Proliferative Breast Disease; N. Engl. J. Med. 1985; 312:146 - 151	
CC2	Lakhani, Sunil R.; The Transition from Hyperplasia to Invasive Carcinoma of the Breast; Journal of Pathology, 187:272 - 278, 1998	

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